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(54) CRUDE DRUG EXTRACT

(57)Abstract:
PROBLEM TO BE SOLVED: To obtain the subject extract which can specify the quality of various crude drugs by using a physical indicator related to the effect of medicine and contribute to the offer of the crude extract of stable quality and the appropriate standardization of medicines by using a soluble silicon compound.
SOLUTION: This extract contains a soluble silicon compound in an amount of 0.05 mg or more in terms of silicon per 1 g of the dry product as an active ingredient. Further, in order to produce a crude drug extract, a crude drug, e.g. Salviae miltiorrhizae radix, garderma lucidum or the like, is used as a raw material. The above raw material is heated in purified water under refluxing and stirring, the unnecessary substance is removed by filtration or the like to obtain an extract, then wen necessary, the extract is concentrated and the residue is treated by spray-drying or freeze-drying under reduced pressure.

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CLAIMS

[Claim(s)]
[Claim 1] The crude drug extract which contains a fusibility silicon compound as an active principle.
[Claim 2] The standardization approach of the crude drug extract which makes a fusibility silicon content an index.

[Translation done.]

DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention] This invention relates to the crude drug extract which contains the silicon compound of fusibility as an active principle, and its standardization approach.
[0002]
[Description of the Prior Art] The living thing which leads a life process consists of cells, and the malfunction in a cell leads a living body to a symptoms condition. Corresponding to change of inner / external environment, a living body adjusts and maintains a living body's physics and chemical condition in a certain certain stable physiological condition, and is maintaining the life as an individual. By the cell membrane, a cell touches an external environment, performs absorption and secretion of various matter through this, receives the stimulus from the outside, reacts, and is maintaining homeostasis in the living body. Especially the thing performed through ion channels, such as various acceptors of cell surface, sodium, a potassium, and calcium, is well known for maintenance and normalization of a living body function. And when the balance of this living body function collapses by a certain cause and it becomes chronic, various kinds of illnesses as the so-called symptoms will be discovered.
[0003] A cell membrane consists of phospholipid bilayer and is bearing the function important for maintenance of lives, such as permselectivity, active transport, generating of bioelectricity, and a manifestation of immunity activity, and complicated. Although a normal cell has a fluidity and it has the self-repair ability to a trauma, by inner / external invasion by too much stressful stimuli, such as a virus and bacterial infection, the fluidity of a cell membrane will fall to aging or various disease lists, and will cause abnormalities at them to constant maintenance of a living body. For example, a vascular endothelial cell and a nerve cell receive a trauma by hyperlipidemia, hypertension, diabetes mellitus, aging, smoking, etc., and it is known well that arteriosclerosis, a kidney disease, peripheral neuropathy, etc. will arise.
[0004] as one of the complicated functional adjustment devices in the living body — a kallikrein-kinin system — the enzyme system is known. About this plasma kallikrein-kinin system, when a blood coagulation XII factor is activated by the trauma and noxious stimulus to a cellular structure, a series of enzyme reaction systems are caused in the living body. That is, it acts on the plasma prekallikrein which similarly exists in plasma, and this is changed into the plasma kallikrein of an active enzyme, subsequently to the giant-molecule kininogen in plasma this plasma kallikrein acts, and the activated active blood coagulation XII factor separates bradykinin.
[0005] The bradykinin which is the generation product of a plasma kallikrein-kinin system has various bioactive, such as a migration operation of teleangiectasia, blood-vessel-permeability sthenia, pain, and a pathogenic ** leucocyte, and is known as a mediator of pain and pathogenic ** allergic response induction. Therefore, by controlling isolation production of too much bradykinin, a pain, inflammation, an allergy symptom, etc. can be eased and it becomes possible to normalize this symptoms condition.
[0006] This plasma kallikrein-kinin system has a meaning important for functional accommodation of a living body with a catecholamine etc. and close relevance in in the living body in the arachidonate cascade list consisting mainly of other various enzyme reaction systems, for example, a renin-angiotensin series, a blood coagulation system, a fibrinolytic system, a complement system, a prostagladin, leukotriene, and thromboxane. Therefore, the kallikrein-kinin system is deeply concerned with the blood pressure regulation operation, the operation which leads a blood coagulation-fibrinogenolysis-complement system, a living body adjustment operation, a peripheral circulation improvement operation by the various active substances in the living body generated by the arachidonate cascade, etc. by being connected with other enzyme systems. Thus, the root plasma kallikrein-kinin system [a living body function] is participating in very various adjustment systems in the living body, and the matter which affects this plasma kallikrein-kinin system is considered with regards to various drug effect.
[0007] this invention person has continued research paying attention to the silicon compound in the living body which adjusts an autonomous operation of a nerve cell, immunization, etc. by the technique using a plasma kallikrein-kinin system. Silicon is widely distributed over the animal and plant kingdoms, it exists in each organ, such as the skin, hair, a bone and lungs, a suprarenal gland, a thymus gland, the pancreas, and a spleen, as a silicic acid especially in an animal tissue at abundance, and it is known by osteogenesis that it is an indispensable component etc. Moreover, in the animal tissue, a collagen cross-linking chain is formed, it is contained as a constituent of an acid mucopolysaccharide object, and it is suggested that the resiliency of the skin is also related to the amount of a silicic acid.
[0008]
[Problem(s) to be Solved by the Invention] Although the crude drug is used for medicine for many years, even if it sees the quality appraisal method of the crude drug which is checked mainly by the experiential extraction method over many years about the quality in many cases, for example, was indicated by the Japanese pharmacopoeia (the thirteenth amendment), there are many things of only color reaction or the verification test by the spot of thin-layer chromatography. Therefore, a setup of the material specification for collateralizing a fixed effect per crude drug was called for strongly. Specifying the quality of various kinds of crude drugs with the material index relevant to drug effect can be contributed to offer of the crude drug extract of the stable quality, and it contributes to suitable standardization of drugs.

[0009]
[Means for Solving the Problem] this invention person completed this invention by specifying the quality of a crude drug paying attention to a living body's silicon compound by making into an index the silicon compound of the fusibility which discovers drug effect in the living body.
[0010] The purpose of this invention is to offer the crude drug extract which contains the silicon compound of fusibility as an active principle, and its standardization approach.
[0011]
[Embodiment of the Invention] This invention is a crude drug extract which contains a fusibility silicon compound 0.05mg or more as an amount of silicon conversions per 1g of hardening-by-drying objects.
[0012] this invention crude drug extract can be extracted and obtained from various crude drugs. For example, Salvia miltiorrhiza Bge., Purple Ganoderma, creeping saxifrage, ****, Eucommia ulmoides, a plantain, a plantago seed, Polyporus, Bupleurum chinense, angericae radix, The sambucus, Poria, the root of a kudzu, a raw aloe, a ginseng radix, ginger, an alisma rhizome, schisandra fruit, 37, Animals-and-plants crude drugs, such as a dried jujube, aurantii nobllis pericarpium, Ophiopogonis tuber, a young deer horn, bezoar bovis, Lumbricus, bear bile, and a keel, can be used, and the animals and plants, the mineral, etc. which fulfills the conditions which the invention in this application specifies can be applied to any crude drug extracts made into the origin. Although water or ethanol, and the suitable extracting solvent that added additives, such as a phenol, to the list can extract these crude drug raw material and a crude drug extract can be manufactured, pH of heating or a solvent can be changed in that case, and an extract and concentration of an active substance can be promoted, for example, the following manufacture approaches can be mentioned.
[0013] 1) Purified water is added to a crude drug raw material, carry out boiling stirring, remove insoluble matter by filtration etc., and obtain an extract (extractives). Subsequently, an extract is condensed if needed, and disintegration of spray dry or the freeze drying under reduced pressure is performed and carried out.
2) Add purified water to a crude drug raw material, and after a boiling stirring extract, double with a previous extract after adding purified water further, adjusting pH to an alkali field (pH8.5 thru/or 10.5, for example, the pH9.5 neighborhood), carrying out a boiling stirring extract again and adjusting this extract near neutrality. Then, the need is accepted like the above 1, an extract is condensed and/or hardened by drying, and disintegration is performed.
3) Add phenolated water to a crude drug raw material 1%, carry out boiling stirring like the above, and obtain an extract. And the need is accepted like the above, and an extract is condensed and/or hardened by drying.
4) Add purified water and ethanol to a crude drug raw material, carry out a boiling stirring extract like the above, and make it be the same as that of the above concentration and hardening by drying if needed.
5) After performing the above 1 thru/or extract operation of 4, adjust pH of an extract to weak alkali (for example, pH8.5 neighborhood), condense it, and carry out disintegration like the above after adjusting pH of concentration liquid subsequently to near neutrality.
[0014] The description is to have specified per content of a fusibility silicon compound, the content of the fusibility silicon compound in the hardening-by-drying object of the crude drug extract obtained by the above-mentioned manufacture approach can be analyzed by the following approaches, and the invention in this application can be specified as an amount of silicon conversions. A crude drug extract is added to water (1 mg/mL), shaking and sonication are performed, after carrying out shaking at a room temperature for 10 minutes preferably and ultrasonicating at a room temperature for 10 minutes subsequently, filtration or centrifugal separation removes insoluble matter, and the silicon content in the obtained solution is measured by the molybdenum blue method. Moreover, the plasma kallikrein generation inhibitory action of the same sample solution is measured, and it checks as an index of fusibility silicon compound activity. The above-mentioned plasma kallikrein generation inhibitory action is important as an index which measures and checks the potency (strength of bioactive) of the fusibility silicon compound which has bioactive.
[0015] this invention crude drug extract — the shape of extractives — or it dried — powdered — physic — it can use as a raw material for physic youthfully, and can consider as physic as it is, without using an additive, or can pharmaceutical-preparation-ize, combining the suitable additive for physic suitably. About pharmaceutical-preparation-izing, by any usual approaches,-izing can be carried out [****] and a prescription can be written to the dosage forms of taking orally or the solid-state for carrying out parenteral administration, a semisolid, or a liquid. In a formula, it is independent in this invention crude drug extract, or good also as a compounding agent which combined or was suitably combined with other chemosynthesis physic active ingredients. [two or more]
[0016] As an internal use agent, extract extractives may be used in a form as it is, and taste agents, such as a buffer, a preservative, and a saccharide, perfume, etc. are added suitably, and-izing can be carried out [****] to desirable dosage forms. When extract extractives are dried and it is made the shape of powder May use desiccation powder in a form as it is, and with or excipients of common use, such as a suitable additive, for example, a lactose, mannite, corn starch, and potatostarch Crystalline cellulose, a cellulosic, gum arabic, corn starch, Binders, such as gelatin, corn starch, potatostarch, It can consider as a tablet, powder, a granule, or a capsule, combining suitably lubricant, such as disintegrator, such as a carboxymethyl-cellulose potassium, talc, and magnesium stearate, other extending agents, a humid-ized agent, a buffer, a preservative, a taste agent, perfume, etc. Moreover, it is also possible to pharmaceutical-preparation-ize according to the class of disease to dosage forms permitted pharmacologically, such as dosage forms other than the optimal above for the therapy, for example, injections, suppositories, inhalations, aerosols, ophthalmic solutions, ointment, and cataplasms.
[0017] Various operation gestalten other than the crude drug extract which specified the silicon compound of fusibility as this invention, such as the process, physic application, etc., are included, and the desirable embodiment of this invention is listed to below.
[0018] (1) The crude drug extract which contains a fusibility silicon compound 0.05mg or more as an amount of silicon conversions per 1g of hardening-by-drying objects.
(2) The crude drug extract of the above-mentioned (1) publication extracted from a kind chosen from the group which consists of animals-and-plants crude drugs, such as Salvia miltiorrhiza Bge., purple Ganoderma, creeping saxifrage, ****, Eucommia ulmoides, a plantain, a plantago seed, Polyporus, Bupleurum chinense, angericae radix, the sambucus, Poria, the root of a kudzu,

a raw aloe, a ginseng radix, ginger, an alisma rhizome, schisandra fruit, 37, a dried jujube, aurantii nobllis pericarpium, Ophiopogonis tuber, a young deer horn, bezoar bovis, Lumbricus, bear bile, and a keel
(3) The crude drug extract of the above-mentioned (1) publication extracted from a kind chosen from the group which consists of Salvia miltiorrhiza Bge., purple Ganoderma, creeping saxifrage, ****, Eucommia ulmoides, a plantain, a plantago seed, Polyporus, Bupleurum chinense, angericae radix, the sambucus, Poria, the root of a kudzu, a raw aloe, and a ginseng radix.
[0019] (4) The above (1) which measured and standardized the amount of the silicon compound which solubilizes and exists in this water solution after adding water (1 mg/mL) to the hardening-by-drying object of a crude drug extract, making it dissolve in it and removing insoluble matter, (2), or a crude drug extract given in (3).
(5) The manufacture approach of the above (1) using the extract by which pH was adjusted to the alkali field thru/or the crude drug extract any one publication of (4).
(6) The manufacture approach of the above-mentioned (5) publication using the extract by which pH was adjusted to 8.5 thru/or 10.5.
(7) The manufacture approach of performing an extraction method the above (5) or given in (6) further after the extracting solvent near neutrality extracts.
(8) The above (5) which removes a solvent and obtains a hardening-by-drying object after heating or boiling a crude drug raw material and extracting it thru/or the manufacture approach of any one publication of (7).
(9) The above (5) using water, ethanol, or those mixed liquor as an extract thru/or the manufacture approach of any one publication of (8).
(10) The manufacture approach of the above-mentioned (9) publication using the extracting solvent which added additives, such as a phenol.
[0020] (11) The standardization approach of the crude drug extract which makes a fusibility silicon content an index.
(12) The approach of the above-mentioned (11) publication which standardizes a crude drug the above (2) or given in (3).
(13) An approach the above (11) which standardizes a crude drug according to the approach of the aforementioned (4) publication, or given in (12).
(14) The approach of the above (11) which standardizes a crude drug combining verification tests, such as color reaction, thru/or any one publication of (13).
[0021] (15) The plasma kallikrein generation inhibitor which contains the above (1) thru/or the crude drug extract of any one publication of (4) as an active principle.
(16) The plasma kallikrein generation inhibitor of the above-mentioned (15) publication which is an antiallergic agent.
(17) The plasma kallikrein generation inhibitor of the above-mentioned (15) publication which is a painkiller.
(18) The plasma kallikrein generation inhibitor of the above-mentioned (15) publication which is an anti-inflammatory agent.
[0022] Hereafter, although an example explains this invention to a detail, these do not limit the range of this invention.
[0023]
[Example] 1. Water was added to the desiccation powder of the quantum crude drug extract of a fusibility silicon compound (1 mg/mL), and it shook at the room temperature for 10 minutes, and after ultrasonicating at a room temperature for 10 minutes subsequently, it filtered using the membrane filter (0.45 micrometers), and the filtrate except insoluble matter was used as a specimen. After adding the sodium hydroxide test solution (1 mol/L) of 0.2mL(s) to this sample-solution 3mL and leaving it overnight, the hydrochloric-acid test solution (1 mol/L) of 0.3mL was added. Subsequently, the ammonium-molybdate solution of 0.1mL(s) (often mix hydrochloric-acid water-solution 64mL which diluted 15g of ammonium-molybdate 4 hydrates 10 times, and it melts) After adding the solution which added water and was set to 200mL(s), mixing with it and leaving it for 5 minutes, The tartaric-acid water solution (170 g/L) of 0.4mL(s) is added, and it mixes with it, and is the 1-amino-2-naphthol-4-sulfonic acid solution (1.4g of dried sodium sulfite) of 0.1mL(s) after 1 minute. It adds, and it mixed with the solution which melted 0.3g of 1-amino-2-naphthol-4-sulfonic acid, and 18g of sodium hydrogensulfites in water, and was set to 200mL(s), and it was made to color. The absorbance in the wavelength of 820nm was measured after about 30-minute neglect, and the quantum of silicon was performed. In the following examples, it was written as the quantum trial and the result (mug/mL) was shown.
[0024] 2. ["a foundation and clinical" which measured the inhibitory action of this invention crude drug extract to plasma kallikrein generation inhibitory action plasma kallikrein generation according to the approach given in reference — the 20th volume, No. 17, and 399 -405-page (1986)]. That is, the kallikrein generation inhibition activity of this specimen material was searched for by adding kaolin suspension to the normal human plasma diluted with the physiological saline, and making the specimen material live together in the system which carries out the quantum of the generated kallikrein using synthetic substrate D-Pro-Phe-Arg-p-nitroaniline, after adding the Lima beans trypsin inhibitor and stopping a kallikrein generation reaction after fixed time amount. The strength of inhibition activity made the index the amount of para nitroaniline which separates from a synthetic substrate by the generated kallikrein, measured the absorbance in 405nm, and showed it according to the absorbance difference with the case (contrast) where the case where the specimen of the above 1 is added, and a specimen material are not added. That is, I hear that kallikrein generation inhibition activity is so strong that an absorbance difference (deltaOD) is large, and it is. In addition, in the case of the specimen material with this very strong inhibition activity, the exam was performed using the sample solution which diluted the above-mentioned specimen (1 mg/mL) suitably, and it showed the result converted into the activity reinforcement of the original sample concentration based on the dilution scale factor. In the following examples, it was written as the activity trial and the result (deltaOD value) was shown.
[0025]
3. Detection of Verification-Test (1) Pentose of Crude Drug Extract Component (Orcinol and Iron(III) Chloride Method)
- Sample solution : melt 0.1g of crude drug extracts to water 10mL.
- Standard solution : melt 0.1mg D-ribose to water 1mL.
- Actuation : to the sample solution and standard solution 1mL, it is easy to add iron(III) chloride solution 3mL and ethanol solution 0.3mL of orcinol, and agitate them. under a water bath — it is — after heating during 25 minutes, and a stream — when it cools in inside, a solution presents green.
- Color reagent : melt 0.1mg of a iron(III) chlorides to hydrochloric-acid 100mL.
b) Melt orcinol 0.1mg to ethanol 100mL.

[0026] (2) Detection of a hexose (anthrone sulfuric-acid method)
- Sample solution : melt 0.1g of crude drug extracts to water 10mL.
- Standard solution : melt 0.1mg D-glucose to water 1mL.
- Add anthrone sulfuric-acid 5mL ice-cooled similarly to the sample solution operated : ice-cooled and standard solution 1mL, and mix. the stream after being under water bath and heating for 10 minutes — when it cools in inside, a solution presents green.
- Color reagent : add to the water of 20mL(s), melting and ice-cooling to sulfuric-acid 100mL which ice-cooled anthrone 0.2g.
[0027] (3) Detection of steroid saponin (Liebermann reaction)
- Actuation : when it is under water bath, and is left in the room temperature after heating for 2 minutes and sulfuric-acid 2mL is quietly added to acetic-anhydride layer 0.7mL of supernatant liquid after being easy to add acetic-anhydride 2mL to 0.1g of crude drug extracts and mixing it with them, an interface presents red - dark reddish-brown, or the upper layer presents blue - green.
[0028] (4) Detection of a carbonyl group content compound (2, 4-dinitrophenylhydrazine)
- Sample solution : it is left, after being easy to add dehydrated ethanol 3mL to 0.1g of crude drug extracts and mixing it with them, and let supernatant liquid be the sample solution.
- Standard solution : melt anisaldehyde 10mg to dehydrated ethanol 3mL, and consider as a standard solution.
- Actuation : when 2, 4-dinitrophenylhydrazine test solution 1mL is added, stirred and left in the sample solution and standard solution 1mL, produce precipitate of yellow - orange.
- Reagent : 2, 4-dinitrophenylhydrazine 1.5g is melted to the cooling mixture of sulfuric-acid 10mL and water 10mL, water is added, and it is referred to as 100mL(s).
[0029] (5) Detection of a phenolic group content compound (iron(III) chloride method)
- Sample solution : it is left, after being easy to add dehydrated ethanol 3mL to 0.1g of crude drug extracts and mixing it with them, and let supernatant liquid be the sample solution.
- actuation: — rare to sample-solution 1mL — add iron(III) chloride test solution 1mL, and a solution wears blue after churning.
- Reagent : melt 9g of rare iron(III) chlorides in water, add water to 2mL(s) of the solution, and make it 100mL(s).
[0030] (6) A check and the sample solution of flavonoid : after adding methanol 10mL to 50mg of crude drug extracts and heating quietly for 2 - 3 minutes, carry out centrifugal, and when adding and leaving ribbon-like magnesium 0.1g and hydrochloric-acid 1mL in supernatant 5mL, liquid presents red.
[0031] (7) An aldehyde, a ketone (2, 4-dinitrophenylhydrazine) and the sample solution : it is left, after being easy to add diluted ethanol 1mL to 0.05g of crude drug extracts and mixing it with them, and let supernatant liquid be the sample solution.
- expansion solvent: — the upper layer and laminated plate [of n-butanol, an acetic acid, and water (4:1:5)]: — silica gel (Merck 5553)
- amount of samples: — 5microL and color reagent: — 2, 4-dinitrophenylhydrazine 0.4g is melted to 2-N hydrochloric acid, and it is referred to as 100mL(s). After developing a sample solution, when spraying and leaving a coloration test solution, yellow - brown are presented.
[0032] (8) A terpene steroid and sugar (anisaldehyde)
- Sample solution : it is left, after being easy to add diluted ethanol 1mL to 0.05g of crude drug extracts and mixing it with them, and let supernatant liquid be the sample solution.
- expansion solvent: — the upper layer and laminated plate [of n-butanol, an acetic acid, and water (4:1:5)]: — silica gel (Merck 5553)
- amount of samples: — 5microL and color reagent: — p-anisic aldehyde 0.5 — add sulfuric-acid 1mL to mL, and make it 20mL (s) by ethanol. After developing a sample solution, when heating for 5 minutes at 105 degrees C after spraying a coloration test solution, blue - purple and gray - black are presented.
[0033] (9) Amine indole derivatives (para dimethylaminobenzaldehyde) and the sample solution : it is left, after being easy to add diluted ethanol 1mL to 0.05g of crude drug extracts and mixing it with them, and let supernatant liquid be the sample solution.
- expansion solvent: — the upper layer and laminated plate [of n-butanol, an acetic acid, and water (4:1:5)]: — silica gel (Merck 5553)
- amount of samples: — 5microL and color reagent: — 1g of para dimethylaminobenzaldehyde — hydrochloric-acid 50mL — melting — further — add the ethanol of 50mL(s). After developing a sample solution, when spraying and leaving a coloration test solution, blue - purple are presented.
[0034]
(10) Detection (Dragendorff's test solution) and the sample solution of a tertiary amine : after adding 50% ethanol 1mL to 0.05g of crude drug extracts, distributing, and processing for 30 minutes by the supersonic wave, the heating extract was carried out for 5 minutes at 60 more degrees C. Next, it applies to centrifugal separation and let the digestive liquor be the sample solution.
- expansion solvent: — the upper layer of an an-butanol, an acetic acid, and water (4:1:5) b methanol and laminated plate: — silica gel 60F254 and amount of samples: — 5microL and color reagent: - actuation: by JP — after developing a sample solution, when spraying and leaving a coloration test solution, yellow - orange are presented.
[0035]
(11) Alkaloid (platinum chloride-potassium iodide test solution) and the sample solution : 50% ethanol 1mL was added to 0.05g of crude drug extracts, and after distributing, and processing for 30 minutes by the supersonic wave, the heating extract was carried out for 5 minutes at 60 more degrees C. Next, it applies to centrifugal separation and let the digestive liquor be the sample solution.
- expansion solvent: — the upper layer of an an-butanol, an acetic acid, and water (4:1:5) b methanol and laminated plate: — silica gel 60F254 and amount of samples: — 5microL and color reagent: - actuation: by JP — after developing a sample solution, when spraying and leaving a coloration test solution, dark reddish-brown is presented.
[0036] (12) An antimony-trichloride coloration object and the sample solution : carry out centrifugal and let digestive liquor be the sample solution, after adding 50% ethanol 2mL to 100mg of crude drug extracts and heating quietly for 2 - 3 minutes.

・展開溶媒：a）ｎ－プロパノール・水（６４：３６）
b）ｎ－ヘキサン・酢酸エチル（３：７）

- Laminated plate : after developing silica gel (a fluorescence agent is entered) and the - actuation:sample solution by UV=365nm, amount:of samples3microL, and color reagent:JP, when spraying a coloration test solution, present blue.
[0037] (13) A ninhydrin coloration object and the sample solution : melt 0.1g of crude drug extracts to water 10mL.
- expansion solvent: -- the upper layer and laminated plate [of n-butanol, an acetic acid, and water (4:1:5)]: -- silica gel (Merck 5553)
- amount of samples: -- 5microL and color reagent: - actuation: by JP -- after developing a sample solution, when carrying out after spraying a coloration test solution, present blue - purple.
[0038] Example 1
1) Purified water 3L was added to 150g of purple Ganoderma, after carrying out a boiling stirring extract for 1 hour, it condensed to about 800 mL(s) under reduced pressure of an extract, and disintegration was carried out by spray dry.
(Quantum trial) 0.650microg/mL(activity trial) 0.772 (verification test) positivity: (3), (4), (7), (8), (9), (10), (11), (12), (13) [0039] 2) Purified water 3L was added to 150g of purple Ganoderma, and the boiling stirring extract was carried out for 1 hour. After having added purified water 3L to residue furthermore, adjusting pH to 9.5 and carrying out a boiling stirring extract similarly for 1 hour, the extract was adjusted to pH7.0, it condensed to about 800 mL(s) under reduced pressure together with the previous extract, and disintegration was carried out by spray dry.
(Quantum trial) 0.737microg/mL(activity trial) 1.440 (verification test) positivity: (3), (4), (7), (8), (9), (10), (11), (12), (13) [0040] 3) Phenolated water 3L was added to 150g of purple Ganoderma, after carrying out a boiling stirring extract for 1 hour, it condensed to about 800 mL(s) under reduced pressure of an extract, and disintegration was carried out by spray dry.
(Quantum trial) 0.682microg/mL(activity trial) 0.608 (verification test) positivity: (3), (4), (7), (8), (9), (10), (11), (12), (13) [0041] 4) Phenolated water 3L was added to 150g of purple Ganoderma, and the boiling stirring extract was carried out for 1 hour. After adjusting an extract to pH8.5, it condensed to about 800 mL(s) under reduced pressure, and after adjusting pH of concentration liquid to 7.0, disintegration was carried out by spray dry.
(Quantum trial) 0.627microg/mL(activity trial) 0.824 (verification test) positivity: (3), (4), (7), (8), (9), (10), (11), (12), (13) [0042] Purified water 3L was added to example 2. creeping saxifrage 150g, and the boiling stirring extract was carried out for 1 hour. After adjusting an extract to pH8.5, it condensed to about 800 mL(s) under reduced pressure, and after adjusting pH of concentration liquid to 7.0, disintegration was carried out by spray dry.
(Quantum trial) 0.388microg/mL(activity trial) 1.184 (verification test) positivity: (1), (2), (3), (6), (8), (9), (10), (11), (12), (13) [0043] Example 3
1) The same extract / concentration hardening by drying as 1 of an example 1 was operated by using Salvia miltiorrhiza Bge. as a crude drug raw material.
(Quantum trial) 0.304microg/mL(activity trial) 1.848 (verification test) positivity: (2), (5), (7), (8), (9), (10), (11), (12), (13) [0044] 2) The same extract / concentration hardening by drying as 2 of an example 1 was operated by using Salvia miltiorrhiza Bge. as a crude drug raw material.
(Quantum trial) 0.347microg/mL(activity trial) 2.268 (verification test) positivity: (2), (3), (5), (7), (8), (9), (10), (11), (12), (13) [0045] Example 4
1) The same extract / concentration hardening by drying as 1 of an example 1 was operated by using **** as a crude drug raw material.
(Quantum trial) 2.700microg/mL(activity trial) 0.716 (verification test) positivity: (2), (6), (8), (10), (11), (12), (13) [0046] 2) The same extract / concentration hardening by drying as 2 of an example 1 was operated by using **** as a crude drug raw material.
(Quantum trial) 2.728microg/mL(activity trial) 0.876 (verification test) positivity: (2), (6), (8), (9), (10), (11), (12), (13) [0047] 3) The same extract / concentration hardening by drying as an example 2 was operated by using **** as a crude drug raw material.
(Quantum trial) 15.93microg/mL(activity trial) 0.996 (verification test) positivity: (2), (6), (8), (9), (10), (11), (12), (13) [0048] Example 5
1) The same extract / concentration hardening by drying as 1 of an example 1 was operated by using Eucommia ulmoides as a crude drug raw material.
(Quantum trial) 1.276microg/mL(activity trial) 0.688 (verification test) positivity: (2), (4), (7), (8), (9), (10), (11), (12), (13) [0049] 2) The same extract / concentration hardening by drying as 2 of an example 1 was operated by using Eucommia ulmoides as a crude drug raw material.
(Quantum trial) 1.805microg/mL(activity trial) 0.880 (verification test) positivity: (2), (3), (4), (7), (8), (9), (10), (11), (12), (13) [0050] The same extract / concentration hardening by drying as an example 2 was operated by using an example 6. plantain as a crude drug raw material.
(Quantum trial) 0.809microg/mL(activity trial) 0.780 (verification test) positivity: (2), (3), (7), (8), (10), (11), (12), (13) [0051] The same extract / concentration hardening by drying as 2 of an example 1 was operated by using an example 7. plantago seed as a crude drug raw material.
(Quantum trial) 0.392microg/mL(activity trial) 0.752 (verification test) positivity: (2), (4), (5), (7), (8), (9), (10), (11), (12), (13) [0052] Example 8
1) The same extract / concentration hardening by drying as 1 of an example 1 was operated by using Polyporus as a crude drug raw material.
(Quantum trial) 0.725microg/mL(activity trial) 0.189 (verification test) positivity: (2), (3), (7), (8), (10), (12), (13) [0053] 2) The same extract / concentration hardening by drying as 2 of an example 1 was operated by using Polyporus as a crude drug raw material.
(Quantum trial) 0.964microg/mL(activity trial) 0.573 (verification test) positivity: (2), (3), (4), (5), (8), (10), (12), (13) [0054] The

same extract / concentration hardening by drying as 2 of an example 1 was operated by using example 9. Bupleurum chinense as a crude drug raw material.
(Quantum trial) 0.281microg/mL(activity trial) 0.434 (verification test) positivity: (2), (3), (8), (9), (10), (11), (12), (13) [0055] The same extract / concentration hardening by drying as 2 of an example 1 was operated by using example 10. angericae radix as a crude drug raw material.
(Quantum trial) 0.077microg/mL(activity trial) 0.164 (verification test) positivity: (2), (8), (9), (10), (12), (13) [0056] Example 11
1) The same extract / concentration hardening by drying as 3 of an example 1 was operated by using the sambucus as a crude drug raw material.
(Quantum trial) 0.203microg/mL(activity trial) 0.090 (verification test) positivity: (2), (3), (8), (9), (10), (11), (12), (13) [0057] 2) The same extract / concentration hardening by drying as 4 of an example 1 was operated by using the sambucus as a crude drug raw material.
(Quantum trial) 0.227microg/mL(activity trial) 0.063 (verification test) positivity: (2), (3), (8), (9), (10), (11), (12), (13) [0058] Example 12
1) The same extract / concentration hardening by drying as 1 of an example 1 was operated by using Poria as a crude drug raw material.
(Quantum trial) 0.969microg/mL(activity trial) 0.055 (verification test) positivity: (2), (3), (4), (7), (8), (12), (13) [0059] 2) The same extract / concentration hardening by drying as 2 of an example 1 was operated by using Poria as a crude drug raw material.
(Quantum trial) 1.711microg/mL(activity trial) 0.084 (verification test) positivity: (2), (3), (4), (8), (10), (11), (12), (13) [0060] Example 13
1) The same extract / concentration hardening by drying as 1 of an example 1 was operated by using the root of a kudzu as a crude drug raw material.
(Quantum trial) 0.118microg/mL(activity trial) 0.071 (verification test) positivity: (2), (3), (5), (6), (8), (9), (10), (11), (12), (13) [0061] 2) The same extract / concentration hardening by drying as 2 of an example 1 was operated by using the root of a kudzu as a crude drug raw material.
(Quantum trial) 0.122microg/mL(activity trial) 0.078 (verification test) positivity: (2), (3), (5), (6), (8), (10), (11), (12), (13) [0062] The same extract / concentration hardening by drying as 1 of an example 1 was operated by using an example 14. raw aloe as a crude drug raw material.
(Quantum trial) 0.536microg/mL(activity trial) 0.074 (verification test) positivity: (2), (5), (8), (12), (13) [0063] The same extract / concentration hardening by drying as 1 of an example 1 was operated by using an example 15. ginseng radix as a crude drug raw material.
(Quantum trial) 0.087microg/mL(activity trial) 0.051 (verification test) positivity: (2), (3), (4), (7), (8), (10), (11), (12), (13) [0064] [Effect of the Invention] By containing the silicon compound of fusibility more than fixed, it is shown that this crude drug extract discovers drug effect, and the crude drug which was ambiguous until now can be standardized for this fusibility silicon compound against an index so that clearly from the result of the example using various kinds of above-mentioned crude drugs. The silicon compound contained in a crude drug extract can be comprehensively specified as an amount of silicon conversions measured by the molybdenum blue method in this invention, although the compound of various classes is included. The matter contained in addition to this depending on the class of crude drug differs variously, and standardization of a still stricter crude drug can also be accomplished, combining suitably the color identification test to these content matter etc.
[0065] From the result of an example, by performing extract operation using the solution (pH9.5 neighborhood) with which pH was adjusted to the alkali field as the extract approach from a crude drug, a upward tendency is accepted in the extraction efficiency of a fusibility silicon compound, and it can mention as the desirable extract approach.
[0066] Thus, this invention can specify the quality of various kinds of crude drugs by making the fusibility silicon compound relevant to drug effect into an index, and since it can be contributed to offer of the crude drug extract of the stable quality, it carries out a great contribution to suitable standardization of drugs.

[Translation done.]